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(54) Title: SPERM-SPECIFIC CATION CHANNEL, CATSPER-4, AND USES THEREFOR

(57) Abstract: Nucleic acid and protein sequences relating to a cation channel which is sperm-specific (CatSper4) are disclosed. The CatSper4 protein is shown to be specifically expressed in sperm. Nucleic acids, vectors, transformed cells, transgenic animals, polypeptides, and antibodies relating to the CatSper4 gene and protein are disclosed. Also provided are methods of in vitro fertilization and contraception, methods of identifying modulators of CatSper4 activity, methods of genotyping subjects with respect to CatSper4, and methods of diagnosing and treating CatSper4-mediated disorders, including infertility. Related business methods are also disclosed.

WO 2004/015066 A3

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/24359

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : C07H 21/02, 21/04; C12N 15/00, 15/09, 15/63, 15/70, 15/74, 5/00, 5/02; G01N 33/53; C12Q 1/68
US CL : 536/23.1, 24/3; 435/320.1, 325, 7/1, 6; 800/13; 530/350, 387.1

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 536/23.1, 24/3; 435/320.1, 325, 7/1, 6; 800/13; 530/350, 387.1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WEST, MEDLINE, BIOSIS, EMBASE, SCISEARCH, CAPLUS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A,E	CARLSON A.E. et al. CatSper1 required for evoked Ca ²⁺ entry and control of flagellar function in sperm. PNAS. 09 December 2003, Vol. 100, No. 25, pages 14864-14868, see entire document.	1-20, 26-100
X	QUILL A. et al. A voltage-gated ion channel expressed specifically in spermatozoa. PNAS. 23 October 2001, Vol. 98, No. 22, pages 12527-12531, see entire document.	1-20, 29-32
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Y		26-28, 33-100
X	REN D. et al. A sperm ion channel required for sperm motility and male fertility. Nature. 11 October 2001, Vol. 413, pages 603-609, see entire document.	1-20, 29-32
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Y		26-28, 33-100

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

02 April 2004 (02.04.2004)

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/24359

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claim Nos.: 21-25 and 101-111
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 21-25 are directed to cells in vivo, the scope of which encompasses a transgenic human, which is non-statutory subject matter. Claims 101-111 are directed to business methods, which are non-statutory.
2. ☐ Claim Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claim Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐
☐

The additional search fees were accompanied by the applicant's protest.
No protest accompanied the payment of additional search fees.